DEPARTMENT OF MANAGED HEALTH CARE

ADOPTION OF EMERGENCY REGULATIONS

California Code of Regulations
Title 28, Article 7, Section 1300.67.01

COVID-19 Diagnostic Testing

(Control No. 2020-COV)

AUTHORITY

Under the authority established in the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act),[1] specifically Health and Safety Code Sections 1341, 1343,1344, 1367, 1367.001, 1367.01, 1367.03 and Government Code section 8550 *et seq*., the Director of the Department of Managed Health Care (Department) proposes to adopt as an emergency regulation section 1300.67.01, "COVID-19 Diagnostic Testing," located in Title 28 of the California Code of Regulations (CCR).

REFERENCE

This regulation is intended to implement, interpret, and/or make specific Health and Safety Code Sections 1367, 1367.01, and 1367.03, and Government Code section 8550, et seq.

NON-DELAY STATEMENT

The Director of the Department has determined the emergency situation addressed by this proposed emergency regulation clearly poses such an immediate and serious harm that delaying action to allow public comment would be inconsistent with the public interest.

Accordingly, the Department did not provide a five-day public notice period prior to submitting the proposed emergency regulation to the Office of Administrative Law. The Department requests the Office of Administrative Law similarly waive its typical five-day notice period.

Time is of the essence in this instance because the State of California is in the midst of a global pandemic due to the SARS-CoV-2 virus, which causes COVID-19. California

[1] California Health and Safety Code Sections 1340, et seq. References herein to "Section" are to sections of the Knox-Keene Act unless otherwise specified.

has seen a recent, significant surge in COVID-19 cases, hospitalizations, and deaths. In the past month, the daily number of confirmed COVID-19 cases in California has nearly tripled and the COVID-19 test positivity rate (i.e., the percentage of tests that are positive for COVID-19) increased from 4.5% to 7.15%, indicating the spread of the virus is increasing rapidly in many areas of the state. Also, the number of people hospitalized due to COVID-19 nearly doubled during the past 30 days.

Testing for COVID-19 is essential to identifying people with COVID-19 and stopping the spread of the virus. The proposed emergency regulation will clarify when California health plans must cover testing, how quickly they must provide testing to their enrollees, and how health plans must reimburse providers for performing COVID-19 testing. Prompt reimbursement of providers will allow them to continue to provide testing to their patients. Any delay in the promulgation of this regulation will increase confusion as to when and how enrollees can obtain a test and intensify the spread of COVID-19 in California, resulting in more cases, more hospitalizations, and ultimately, more deaths from the virus.

FINDING OF EMERGENCY

The Director of the Department has determined an emergency exists. Immediate action is necessary to avoid serious harm to the public health and safety.

On January 31, 2020, the United States Department of Health and Human Services Secretary Alex A. Azar declared a public health emergency for the United States to aid the nation's healthcare community in responding to the coronavirus disease (COVID-19). The United States Centers for Disease Control and Prevention (CDC) has declared COVID-19 a worldwide pandemic due to its global effect. On March 13, 2020, President Donald Trump invoked the Stafford Act and declared a national emergency regarding the COVID-19 outbreak.

On March 4, 2020, Governor Gavin Newsom declared an emergency in the state of California in response to the outbreak of respiratory illness due to the novel coronavirus known as COVID-19. On March 19, 2020, Governor Newsom issued Executive Order N-33-20, a stay-at-home order to protect Californians and slow the "rapid spread" of COVID-19. The order mandates all residents heed current public health directives, fundamentally ordering all but the most essential workers to stay home. While some stay-at-home directions were subsequently modified, as recently as July 13, 2020, Governor Newsom announced reinstatement of some restrictions in order to slow the spread and address the spike in new COVID-19 cases.

As of July 13, 2020, California has 320,804 cases of COVID-19, and California has 7,017 deaths resulting from COVID-19. Both of these numbers are rising every day. The current and ongoing public health emergency related to COVID-19 necessitates the proposed regulation to avoid serious harm to public health and safety. The CDC states the COVID-19 virus apparently spreads "easily and sustainably" in the community. Reports suggest an asymptomatic infected person may unknowingly spread the virus to

dozens of other individuals. The Department is aware of media coverage describing Californians' varying experiences obtaining coverage for COVID-19 diagnostic tests, and the confusion among health care service plans regarding requirements for them to cover COVID-19 diagnostic testing. Health officials continue to research and evaluate the crisis, but reports suggest robust testing is necessary to stop the spread of COVID-19 and recover from the public health emergency.

The proposed regulation is necessary to ensure appropriate coverage of and payment for diagnostic testing to address the rapid spread of COVID-19 and take appropriate responsive measures.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Under existing law, the Knox-Keene Act provides for the licensure and regulation of health care service plans by the Department and makes a willful violation of the Knox-Keene Act a crime. The Knox-Keene Act requires health care service plans to provide all basic health care services, to make services readily available at reasonable times, to employ and utilize the allied health workforce to provide services, and to furnish services in a manner providing continuity of care and ready referral of patients, consistent with good professional practice.

The FFCRA and the CARES Act

The federal Families First Coronavirus Response Act (FFCRA) was enacted on March 18, 2020. Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for certain items and services related to diagnostic testing for the detection of SARS-CoV-2 or the diagnosis of COVID-19 (referred to in this document as COVID-19) when those items or services are provided on or after March 18, 2020, and during the applicable federal emergency period. Under the FFCRA, plans shall provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance) or prior authorization or other medical management requirements.

The federal Coronavirus Aid, Relief and Economic Security Act (CARES Act) was enacted on March 27, 2020. Section 3201 of the CARES Act amended section 6001 of the FFCRA to include a broader range of diagnostic items and services that plans shall cover without any cost-sharing requirements or prior authorization or other medical management requirements. Additionally, section 3202 of the CARES Act generally requires health plans providing coverage for these items and services to reimburse any provider of COVID-19 diagnostic testing an amount that equals the negotiated rate or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on a public website. (The plan or issuer may negotiate a rate with the provider that is lower than the cash price.)

SPECIFIC PURPOSE AND NECESSITY OF THE PROPOSED EMERGENCY REGULATION

Subdivision (a) is added to clarify the applicability of the regulation by specifying it pertains to full-service health care service plans offering group or individual coverage, including grandfathered plans. This subdivision specifies that Medi-Cal managed care plans are not subject to the proposed regulation. This provision is necessary to ensure health plans understand the scope of the proposed regulation.

Subdivision (b) is added to define key terms in the proposed regulation. It is necessary to ensure clarity and consistent application of the proposed regulation, and to ensure that health plans understand what is necessary for compliance with the proposed regulation.

More specifically, the definition of "relevant state of emergency" as the emergency declared in California by Governor Newsom is necessary because COVID-19-related emergencies have been declared at both local and national levels. This definition clarifies the relevant emergency to which this proposed regulation applies.

The definition of "clinic" by reference to an existing statutory definition is necessary to clarify the scope of testing sites subject to the proposed regulation.

The definition of "COVID-19" clarifies that the virus associated with the relevant public emergency is the disease caused by SARS-CoV-2. This definition is necessary to ensure that the subject of the proposed regulation is sufficiently clear and consistent with descriptions used by public health authorities such as the World Health Organization (WHO) and CDC.

The definition of "diagnostic testing" is necessary to clarify what tests must be covered by health plans pursuant to the proposed regulation, consistent with referenced federal testing provisions, as well as state guidelines pursuant to the relevant state of emergency and this proposed regulation. This definition is necessary to provide health plans the information necessary to comply with this proposed regulation.

The definition of "essential worker" is necessary to clarify the individuals for which diagnostic testing for COVID-19 is a medically necessary basic health care service, regardless of whether the individual is symptomatic and regardless of whether the individual may have been exposed to a person with COVID-19. The proposed definition of "essential worker" includes certain workers in the emergency and health care sectors, certain workers in settings with vulnerable persons (e.g., elderly persons), workers in settings where social distancing is impracticable, workers in correctional facilities, certain workers who have broad contact with members of the public (e.g., food services and public transportation), and workers in the education sector. This definition of essential worker is necessary to ensure workers whose work environment and responsibilities create a risk of being exposed to COVID-19, or that involve a particular

risk of spreading COVID-19 to the public and to vulnerable persons, receive coverage for diagnostic testing.

The definition of “testing provider” as any professional person, organization, health facility, or other person or institution licensed or authorized by the state to deliver or furnish COVID-19 diagnostic tests, as specified, is necessary to clarify which health care service providers may administer tests that are subject to the proposed regulation. This specific definition is necessary to clarify relevant testing providers include not only primary care providers, urgent care centers, and other familiar health care providers, but also others who are performing COVID-19 diagnostic tests during the relevant public emergency: e.g., university laboratories, state-run clinics and testing sites, etc. This definition is necessary to ensure there is no delay in covering diagnostic testing pursuant to this proposed rule.

Subdivision (c) is added to specify that during the relevant state of emergency, diagnostic testing for COVID-19 is a medically necessary basic health care service for enrollees who are essential workers. As defined in subdivision (a)(5), essential workers are generally those individuals whose jobs put them in broad contact with the public or certain vulnerable populations and include workers who may be unable to perform their jobs while maintaining social distancing. The nature of the essential worker’s job and workspace renders the diagnostic test medically necessary, in the context of the public health emergency.

Subdivision (c) is necessary to ensure that health plans cover COVID-19 diagnostic testing for their enrollees who are essential workers, allowing early identification of essential workers with COVID-19 and prompt action to limit these workers from inadvertently spreading COVID-19. Subdivision (c) also specifies that a health plan may not impose “utilization management requirements” (UM) on COVID-19 tests for essential workers, and may inquire only as to whether an enrollee is an essential worker, without requiring specific evidence of that status. These provisions are necessary to avoid delays in diagnostic testing of essential workers, and are intended to help promote prompt testing to mitigate the spread of COVID-19.

Subdivision (c)(2) is added to specify that for enrollees who are <u>not</u> essential workers, health plans may impose ordinary UM permitted by the Knox-Keene Act to determine whether a COVID-19 test is medically necessary. This provision is necessary to clarify that, where the enrollee is not an essential worker, as defined, the health plan may perform appropriate UM, if the enrollee is not experiencing COVID-19 symptoms and has not had known or suspected exposure to someone with COVID-19. This provision is necessary to ensure that diagnostic testing efforts focus on individuals who need the test most.

Subdivision (c)(3) is added to specify that health plans may impose cost-sharing (e.g., copayments or coinsurance) for COVID-19 diagnostic testing, unless otherwise specified by state or federal law, but that a testing provider may waive co-payment or co-insurance. This provision is necessary because some COVID-19 diagnostic tests

must be covered without cost-sharing, pursuant to the FFCRA and CARES Act. Given that context, it is necessary for proposed subdivision (c)(3) to clarify cost-sharing may be imposed for *other* COVID-19 diagnostic testing that may fall outside the reach of relevant federal law. The provision specifying testing providers may waive co-payments and co-insurance is necessary to ensure testing providers understand what cost-sharing amounts they may decline to charge an enrollee.

Subdivision (c)(4) is added to specify when a health plan may deny coverage for a COVID-19 diagnostic test. This subdivision states a health plan may deny coverage if the enrollee failed to attempt to access a COVID-19 diagnostic test from an in-network provider or failed to contact the health plan to locate an in-network testing provider before accessing a COVID-19 test through a non-contracted provider, unless otherwise specified by state or federal law. This provision is necessary because health plans typically arrange health care services through a network of providers. Using provider networks helps provide certainty for and containment of health care costs. Subdivision (c)(4) is necessary to ensure individuals attempt to seek COVID-19 testing in-network, which will help mitigate the cost of this public health emergency.

Subdivision (c)(5) is added to specify that medically necessary COVID-19 testing is "urgent care" pursuant to existing section 1300.67.2.2 of Title 28 of the California Code of Regulations. This provision is necessary because medically necessary COVID-19 testing must be performed promptly to mitigate the spread of the virus and reduce the effects of the public health emergency. It is therefore necessary to apply the appointment wait-time standard for urgent services (48 hours) to ensure prompt COVID-19 diagnostic testing.

Subdivision (c)(5)(A) further clarifies when an enrollee may seek a COVID-19 diagnostic test from an <u>out-of-network</u> provider, by specifying the circumstances under which such testing is permitted. When the health plan cannot offer a timely appointment within reasonable proximity to the enrollee's residence or workplace (i.e., 15 miles or 30 minutes, which is an existing geographic access standard), an enrollee may seek a test out of network.

Subdivision (c)(5)(B) complements subdivision (c)(4)(A), identifying when out-of-network COVID-19 tests must be covered. This is necessary to ensure enrollees can access COVID-19 testing in a timely fashion, and to allow health plans to understand how to comply with the proposed rule. Finally, subdivision (c)(5)(B) specifies that health plans will reimburse providers for COVID-19 diagnostic testing at the contracted rate. If there is no contracted rate, the health plan will reimburse the provider for the provider's cash price for the test when required by federal law. In all other cases, the health plan will reimburse the provider at the "reasonable and customary value," as set forth in existing regulations. This provision is necessary to provide clarity on how much the health plan must reimburse providers for COVID-19 tests.

Subdivision (d) is added to address delegation of financial risk for diagnostic tests. This provision is necessary because it is common for heath plans to delegate risk to other

entities. For example, a health plan may agree to pay the medical group a flat per-enrollee, per-month amount (capitation), whereby the medical group is responsible for providing necessary care to the health plan's enrollees assigned to the medical group. That medical group has taken on "risk" because it is possible the cost of necessary care will exceed the amount of capitation it receives from the health plan. Subdivision (d) is necessary to ensure health plans do not shift the financial risk for COVID-19 tests pursuant to the proposed rule without treating that shift as a material change to the parties' contract. This is necessary to ensure the parties negotiate and agree upon the new contractual provision in accordance with the Health Care Providers' Bill of Rights (Health and Safety Code section 1375.7). This subdivision is necessary to ensure contracted providers take on financial risk for COVID-19 tests only under specifically negotiated terms, and with appropriate notice.

Subdivision (e) is added to specify timeframes for submission and payment of claims for COVID-19 diagnostic testing and related items and services to avoid delays in reimbursement for providers conducting tests. Health care providers have reported financial strain due to the public health emergency, and delayed reimbursement could cause further strain and threaten the financial viability of some health provider operations. Accordingly, subdivision (e) clarifies the timeframes for claims submission and payment specified in existing law also apply for the purpose of the proposed rule.

Subdivision (e)(2) further specifies that a health plan shall not delay or deny payment of a testing provider's claim: (A) due to delegation of claims payment functions to another entity, or related disputes; or (B) for testing of enrollees who are essential workers, if the plan has specified information. These provisions are necessary to clarify how this proposed regulation fits into existing claims payment laws that require a "complete" claim, and to address two likely sources of delay in reimbursement for COVID-19 tests.

First, subdivision (e)(2)(A) is necessary to ensure a health plan's delegation arrangement does not delay reimbursement to a testing provider. This provision is necessary to implement Health and Safety Code section 1367, which holds a health plan ultimately responsible for compliance with the law, notwithstanding the health plan's delegation of functions to another entity. Accordingly, this subdivision requires prompt payment without delay or denial due to the health plan's delegation to another entity.

Second, subdivision (e)(2)(B) is necessary to ensure testing of enrollees who are essential workers, as defined, is not delayed. As stated previously, essential workers include those workers whose prompt testing may help stop the spread of COVID-19. Subdivision (e)(2)(B) clarifies that reimbursement for testing may not be delayed or denied on the basis the claim is "incomplete," as long as the plan has information sufficient to establish the essential worker was enrolled with the health plan at the time of testing, and the plan received a statement that the enrollee is an essential worker.

Subdivision (e)(3) clarifies, for the purpose of claims submission, "provider" includes the State of California, university laboratories, and state- or county-run clinics or other

testing sites. This provision is necessary because there are broad efforts underway to increase COVID-19 diagnostic testing in California, including through state-run testing sites. Thus, testing providers pursuant to the proposed rule include providers who may not typically submit claims to health plans. This provision in (e)(3) clarifies these providers are included. This will allow health plans to understand how to comply with the proposed rule's claims submission and payment requirements.

Subdivision (f) is added to specify that failure of a health plan to comply with the proposed rule may constitute a basis for disciplinary action, pursuant to the Knox-Keene Act. This provision is necessary to clarify that failure to comply with the proposed rule is actionable and will help ensure health plans comply.

BROAD OBJECTIVES AND BENEFITS OF THE PROPOSED EMERGENCY REGULATION

Pursuant to Government Code section 11346.5(a)(3)(C), the broad objectives and benefits of this proposed regulation, are to increase diagnostic testing in order to slow the spread of COVID-19, and to provide health plans, consumers, providers and other stakeholders clear direction on requirements for coverage of COVID-19 diagnostic testing and claims reimbursement. The CDC advised that COVID-19 seems to be spreading easily and sustainably in many communities. Given the public health implications of an increasing number of cases, it is essential that questions about coverage and cost-sharing not create a barrier to testing for COVID-19.

This regulation specifies, during the relevant state of emergency, COVID-19 diagnostic testing is a medically necessary basic health care services for all essential workers, as defined, and prevents delays in testing and claims payment related to such individuals. The regulation will have the benefit of enabling the testing of more Californians who have broad contact with the public or with vulnerable populations, or whose work environment does not allow social distancing. Increased testing of such individuals, including asymptomatic individuals with no proven exposure to COVID-19, will result in prompt identification of new COVID-19 cases. This will allow the affected individuals to take appropriate action to limit exposure of others to the virus, and stop the spread of COVID-19.

DOCUMENTS RELIED UPON

- Families First Coronavirus Relief Act, Pub. L. No. 116-127 (2020).
- Coronavirus Aid, Relief and Economic Security Act, Pub. L. No. 116-136 (2020).
- Executive Department, State of California, Proclamation of a State of Emergency, published March 4, 2020.
- Executive Department, State of California, Executive Order N-33-20, dated March 19, 2020.CDC FAQs, available at www.cdc.gov/coronavirus/2019-ncov/faq.html#Spread.

- Esbin, M.N., *et al.* (2020) Overcoming the bottleneck to widespread testing: a rapid review of nucleic acid testing approaches for COVID-19 detection. *RNA*. doi.org/10.1261/rna.076232.120. Source: Howard Hughes Medical Institute. Widespread testing could help stop the spread of COVID-19. Available here: https://www.news-medical.net/news/20200618/Widespread-testing-could-help-stop-the-spread-of-COVID-19.aspx

FISCAL IMPACT

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The proposed regulation does not impose a mandate on local agencies and school districts. No other direct or indirect costs or savings to local agencies or school districts required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of the Government Code, or other non-discretionary costs or savings imposed on local agencies are applicable. There is no direct cost or savings in federal funding to the state.

COSTS OR SAVING TO STATE AGENCY

There are no costs or savings to a state agency as a result of the proposed regulation.

COST OR SAVINGS IN FEDERAL FUNDING

Pursuant to Government Code section 11346.5, subdivision (a)(6), the Department has determined that this regulation will have no direct cost or savings in federal funding to the state. However, the State's efforts to seek reimbursement from private health insurance may assist the State in seeking COVID-19-related funding from the Federal Emergency Management Agency (FEMA).

CONSISTENCY WITH STATE LAW

Pursuant to Government Code section 11346.5, subdivision (a)(3)(D), the proposed regulation was evaluated and was not found to be inconsistent 11346.5 or incompatible with existing state regulations contained in Title 28 of the California Code of Regulations.

COMPARABLE FEDERAL LAW

The proposed regulation is not inconsistent with comparable federal law. Certain sub-regulatory federal guidance related to the FFCRA and CARES Act states the federal law requires coverage of COVID-19 diagnostic testing, without cost-sharing or medical management, for individuals who are symptomatic or have been exposed to COVID-19, and clarifies that neither FFCRA nor the CARES Act prevent a state from imposing additional standards related to COVID-19 diagnosis or treatment. The emergency

regulation proposed in this action pertains to diagnostic testing for individuals who are symptomatic or have been exposed to COVID-19 pursuant to federal sub-regulatory guidance, as well as other individuals, as specified.

DETERMINATION

The Department has not identified any reasonable alternative nor has any stakeholder brought to the attention of the Department any alternative that would be more effective in carrying out the purpose for which the above action is proposed, or would be as effective and less burdensome to affected private persons, than the proposed action.

REQUIRED NOTICE OF PROPOSED EMERGENCY RULEMAKING ACTION

This statement confirms that the Department complied with the requirement to provide notice of the proposed emergency action pursuant to Government Code section 11346.1, subdivision (a)(2).

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